JUN 2 6 2001

K011554

BIOMET

CORPORATE HEADQUARTERS

Summary of Safety and Effectiveness

Applicant/Sponsor: Biomet, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0578

Distributor: Walter Lorenz Surgical, Inc.
1520 Tradeport Drive
P.O. Box 18009
Jacksonville, Florida 32229-8009

Contact Person: **Patricia Sandborn Beres**
Biomet Orthopaedics, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0578
Phone: (219) 267-6639
Fax: (219) 372-1683

Proprietary Name: Lorenz LactoSorb® Vocal Medialization Implant

Common Name: Thyroplasty Implant (21 CFR 874.3620)

Legally Marketed Devices to Which Substantial Equivalence is Claimed: Silicone VoCoM® System (K974311 & K000533); Montgomery Thyroplasty Implant System (K972317); and GORE ReVox Thyroplasty Implants (K983525).

Device Description: The Lorenz LactoSorb® Vocal Medialization Implant is a one-piece device consisting of a cloverleaf base and triangular wedge top. The top is available in 5 sizes for males and five for females. The different sizes correspond to the height of the triangular portion of the implant and the displacement caused by the implant. Male and female implants differ in the length of the triangular top, the base sizes are identical. The base has holes around the outer edge to facilitate attachment to the surrounding cartilage using prolene suture.

The LactoSorb® Vocal Medialization Implant are made from LactoSorb® resorbable, 82% L-lactide/18% glycolide copolymer, which degrades by hydrolysis into l-lactic and glycolic acid. These hydrolytic products are further degraded into carbon dioxide and water via the cellular Krebs cycle.

Intended Use: The Lorenz LactoSorb® Vocal Medialization Implant is indicated for medialization thyroplasty in patients with unilateral vocal cord paralysis to improve voice quality.

Summary of Technologies:

	Lorenz LactoSorb® Vocal Medialization Implant	VoCoM® System	Montgomery Thyroplasty Implant System	Gore ReVox Thyroplasty Implant
Manufacturer	Walter Lorenz Surgical, Inc.	Smith & Nephew, Inc.	Boston Medical Products	W.L. Gore & Associates, Inc.
510(k) #	New	K974311 & K000533	K972317	K983525
Material	LactoSorb®	Hydroxlapatite	Silicone	ePTFE
Indications for Use	Medialization thyroplasty in patient with unilateral vocal cord paralysis to improve voice quality	Medialization of a paralyzed vocal cord	Medialization thyroplasty in patient with unilateral vocal cord paralysis to improve quality of vocalization	Medialization thyroplasty in patient with unilateral vocal cord paralysis to improve voice quality
Design	Prefabricated – Cloverleaf base with triangular top	Prefabricated - Rectangular wedge with available shims	Molded in surgery – 3 tiered base obtuse triangular top	Prefabricated – Long thin strips
Thicknesses	8,9,10,11,12mm (for males) 6,7,8,9,10mm (for females)	3,4,5,6,7,8mm	8,9,10,12mm (for males) 6,7,8,9,10mm (for females)	"variety of sizes"
Method of attachment	Suture	Press-fit	Press-fit	Suture

Non-Clinical Testing: An animal study was undertaken which demonstrated the acceptability of a LactoSorb® implant for medialization thyroplasty.). This study concluded that a LactoSorb® implant is ideal for vocal fold medialization for an intermediate (1-4 months) time frame. The implant was completely resorbed by 6 months with medialization being maintained at 9 months secondary to an increase in muscle bulk.

Clinical Testing: None

LactoSorb is a trademark of Biomet, Inc.
VoCoM is a trademark of Smith & Nephew, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 6 2001

Biomet Orthopaedics, Inc.
c/o Ms. Patricia Sandborn Beres
P.O. Box 587
Warsaw, Indiana 46581-0578

Re: K011554
Trade Name: Lorenz LactoSorb® Vocal Medialization Implant
Regulation Number: 874.3620
Regulatory Class: II
Product Code: 77 MIX
Dated: May 17, 2001
Received: May 18, 2001

Dear Ms. Beres:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): K011554

Device Name: LactoSorb® Vocal Medialization Implant

Indications For Use: The Lorenz LactoSorb® Vocal Medialization Implant is indicated for medialization thyroplasty in patients with unilateral vocal cord paralysis to improve voice quality.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K011554

060003